FDA requires stronger warnings about rare but serious incidents related to sleep medications

*Updated warnings for eszopiclon (*Lunesta*) zaleplon (*Sonata*) and zolpidem(*Ambien, Ambien CR, Edluar, Intermezzo, and Zolpimist).

At the end of April 2019, The U.S. Food and Drug Administration announced that the agency's most prominent warning will now be required on certain prescription insomnia drugs. The warning follows FDA's review of 66 cases of serious injuries and/or deaths resulting from various complex sleep behaviors after taking these medicines. These complex sleep behaviors have included falls, burns, near-drowning, exposure to extreme cold temperatures leading to loss of limb or near death, self-injuries such as gunshot wounds, carbon monoxide poisoning, fatal motor vehicle collisions with the patient driving and suicide. The new warnings will be required for eszopiclone (Lunesta), zaleplon (Sonata) and zolpidem (Ambien, Ambien CR, Edluar, Intermezzo, and Zolpimist).

"While these incidents are rare, they are serious and it's important that patients and health care professionals are aware of the risk. These incidents can occur after the first dose of these sleep medicines or after a longer period of treatment, and can occur in patients without any history of these behaviors and even at the lowest recommended doses," said FDA Acting Commissioner Ned Sharpless, M.D. In addition to the warning, the agency is requiring the addition of a contraindication to not use these medicines in patients who have experienced an episode of complex sleep behaviors after taking them. The warning and contraindication are intended to make the warning more prominent and reflect the risk of serious injury and death.